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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,095	10/06/2006	Gerd Bayer	117163.00157	8142

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EXAMINER	
BAYS, PAMELA M	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,095	BAYER ET AL.	
	Examiner	Art Unit	
	Pamela M. Bays	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 26 March 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on co-pending Application No. 10/561,774, has been reviewed and is NOT accepted.

2. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

> The petitioner/owner name is missing and must be included and, therefore, supplemental terminal disclaimers are required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the new Claim 1 limitation "wherein the coating comprises a polysaccharide layer ... applied directly to the base body" must be shown or the feature(s) canceled from the claim(s). Figs. 1 and 2 clearly show an intermediate layer 12 between the base body 11 and the polysaccharide layer 17. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

6. Regarding Claims 1 and 18-20, the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Amended Claim 1 includes the limitation "wherein the coating comprises a polysaccharide layer made of hyaluronic acid and/or hyaluronic acid derivatives *applied directly to the base body*." Regarding Claims19-20, the "Exemplary Embodiment 3: Chitosan as Adhesion Promoter" (Pages 14-15 of the Specification) describes a method

as shown in Fig. 1 wherein an adhesion-promoting chitosan layer is applied directly to the base body of an electrode, and then the hyaluronic acid or hyaluronic acid derivative layer is added on top of that layer, and dependant Claims 19-20 include the limitation "wherein the polysaccharide layer comprises an adhesion-promoting layer made of chitosan." In addition, dependant Claim 18 includes the limitation “wherein the polysaccharide layer is immobilized covalently or through physiorption on the surface of the stimulation electrode,” explained in “Exemplary Embodiment 1: Covalent Bonding" (Pages 12-13 of the Specification) to describe adhesion to an intermediate layer (Fig. 2) that was between the base body and the polysaccharide layer. It is impossible according to the specification for both of the limitations of Claim 1 and the limitations of Claims 18-20 to be true, for both the intermediate and the polysaccharide layers to be applied directly to the base body, and therefore would not enable one skilled in the art to make or use the invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al (US Patent No. 5,866,113) in view of Balazs et al (US Patent No. 4,487,865).

9. Regarding Claim 1 and 17, Hendriks et al discloses a medical device such as "nerve electrodes, muscle electrodes, implantable pulse generators ...and defibrillators," (Col. 4, Lines 13-15), of which would inherently have a metallic base body, of a biocompatible substance (Col. 3, Lines 7-9). In addition, Hendriks et al discloses that a bimolecular coating to the medical device (Col. 3, Lines 7-9) can include "hyaluronic acid" (Col. 4, Line 37), a polysaccharide, which could be in the form of individual substances, copolymers or block polymers ("polymerized biomolecules," Col 4, Lines 46-49). However, Hendricks et al does not disclose that the hyaluronic acid coating is applied directly to the base body, instead using a surface graft matrix to promote adhesion. Balazs et al teaches a polymeric coating for implanted medical devices such as pacemaker leads containing hyaluronic acid (Col. 1, Lines 20-35), wherein the coating is applied directly to the body of the implant (Col. 1, Lines 40-50), immobilizing the layer covalently or by physisorption (Col. 2, Lines 10-30, Col. 3, Lines 1-10). It would have been obvious to one having ordinary skill in the art at the time of the invention to not use the surface graft matrix as disclosed by Hendriks et al and simply directly coat the implant with the hyaluronic acid polymer, in order to eliminate the resources and time needed for producing and implementing the surface graft matrix.

10. Regarding Claims 2 and 3, Hendriks et al and Balazs et al discloses the claimed invention as described above except for the molecular weight of the hyaluronic acid after a sterilization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer properties by selecting hyaluronic acid with the appropriate molecular weight for the purpose of tissue compatibility, since

it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claims 4 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Balazs et al, in further view of Pastorello (U.S. Patent No. 6,642,213).

12. Regarding Claims 4, 5, and 7, Hendriks et al and Balazs et al disclose a stimulation electrode with a polysaccharide layer coating, with inherent internal and external areas, as described above. However, Hendriks et al and Balazs et al do not disclose the rate of degradation of the layer. Pastorello teaches an implantable medical prosthesis containing a hyaluronic acid derivative (Col.2, Lines 45-48), and that "the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification [has] the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed" (Col. 3, Lines 57-61). It would have been obvious to one of ordinary skill in the art at the time of the invention to select the appropriate chemical structure and degree of esterification of the hyaluronic acid to control the rate of in vivo degradation, as taught by Pastorello, for use in the stimulation electrode disclosed by Hendriks et al and Balazs et al in order to limit the external area to less than 100 days and prolong the internal area to greater than two years in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Regarding Claims 6 and 8, Hendriks et al, Balazs et al, and Pastorello describe a stimulation electrode with a variably degradable polysaccharide layer coating as described above. However, Hendriks et al, Balazs et al, and Pastorello do not disclose the thickness of the internal or external portions of the polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

14. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Balazs et al, further in view of Pastorello, and further in view of Lahtinen (U.S. 2003/0059463).

15. Regarding Claim 9, Hendriks et al, Balazs et al, and Pastorello describe a stimulation electrode with a variably degradable polysaccharide layer coating as described above. However, they do not disclose multiple partial layers of a polysaccharide layer each having different degradation behaviors, the degradation behavior within each partial layer being able to be fixed continuously changeably or constant over the partial layer. Lahtinen teaches that "biocompatible-polymeric carrier matrix, such as alginate, collagen, hyaluronic acid" (Page 13, Paragraph 112, Col. 2, Bottom) can be added to a medical device, and that, "Several layers of polymers can be

utilized and several different polymers can be combined on the same implant... Also, one or more surfaces of the implant can be coated with one or more additional coats of polymer that is the same or different from the second polymer" (Page 14, Paragraph 112, Col. 1, Mid-page). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add multiple hyaluronic acid layers with different degradation properties by altering the chemical structure and degree of esterification of the hyaluronic acid, as taught by Pastorello and Lahtinen, for the purpose of providing different degradation behaviors on coating of the electrode as disclosed by Hendriks et al and Balazs et al to promote tissue compatibility.

16. Regarding Claims 10 and 12, Hendriks et al, Balazs et al, Pastorello, and Lahtinen describe a stimulation electrode with a variably degradable polysaccharide layer coating comprising of multiple partial with different degradation behavior in multiple layers as described above. However, they do not describe weight-percent degradation of the layers during specific time intervals. It would have been obvious to one of ordinary skill in the art at the time of the invention to select the appropriate chemical structure and degree of esterification of the hyaluronic acid to control the rate of in vivo degradation by weight percent, as taught by Pastorello, of each layer in the polysaccharide coating as taught by Lahtinen, in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. Regarding Claims 11, and 13-15, Hendriks et al, Balazs et al, Pastorello, and Lahtinen describe a stimulation electrode with a variably degradable polysaccharide layer coating comprising of multiple partial with different degradation behaviors layers as described above. However, they do not disclose the thickness of the internal or external portions of the polysaccharide layer, or of the entire layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

18. ***Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Balazs et al, further in view of Prutchi (U.S. Patent No. 6,152,882).***

19. Regarding Claim 16, Hendriks et al and Balazs et al disclose a stimulation electrode with a polysaccharide layer coating as described above. However, Hendriks et al and Balazs et al do not disclose the addition dexamethasone and/or dexamethasone sodium phosphate (DMNP) in a concentration sufficient to produce a pharmacological effect. Prutchi teaches a catheter (Fig 9) with an electrode 122 including a steroid drug that "may be a sodium salt of dexamethasone phosphate" (Col. 21, Lines 67-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a steroid drug such as DMNP to an implantable electrode, as taught by Prutchi, for the purpose of improving tissue compatibility in the electrode as disclosed by Hendriks et al and Balazs et al.

20. Claims 19-23 are rejected 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Balazs et al, further in view of Lahtinen, and further in view of Collombel (U.S. Patent No. 5,166,187).

21. Regarding Claims 19, 21, and 23, Hendriks et al discloses a medical device such as "nerve electrodes, muscle electrodes, implantable pulse generators, ...and defibrillators" (Col. 4, Lines 13-15) with various layers (Fig. 3)) to "promot[e] tissue integration" (Col. 1, Line 39). In addition, Hendriks et al discloses that a bimolecular coating to the medical device (Col. 3, Lines 7-9) can include "hyaluronic acid" (Col. 4, Line 37). However, Hendriks et al does not disclose the polysaccharide layer comprises an adhesion-promoting layer or partial layers made of chitosan. Lahtinen teaches that "biocompatible-polymeric carrier matrix, such as alginate, collagen, hyaluronic acid" (Page 13, Paragraph 112, Col. 2, Bottom) can be added to a medical device, and that, "Several layers of polymers can be utilized and several different polymers can be combined on the same implant... Also, one or more surfaces of the implant can be coated with one or more additional coats of polymer that is the same or different from the second polymer" (Page 14, Paragraph 112, Col. 1, Mid-page). Moreover, Collombel teaches the usage of chitosan in a biomaterial to use as a "cross-linking agent" (Col. 8, Lines 47-48) for adhesion, and also including hyaluronic acid to promote cell adhesion and biocompatibility (Col. 8, Lines 62-65). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to add both hyaluronic acid and chitosan to a coating, in layers or partial layers, as taught by Lahtinen and Collombel, in order to promote biocompatibility and cell adhesion to an electrode implant.

22. Regarding Claim 20, Hendriks et al, Balazs et al, Lahtinen, and Collombel disclose a polysaccharide layer coating comprising of hyaluronic acid and chitosan as described above. However, they do not disclose the thickness of the chitosan polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode to best promote biocompatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

23. Regarding Claim 22, Hendriks et al, Balazs et al, Lahtinen, and Collombel disclose a polysaccharide layer coating comprising of hyaluronic acid and chitosan as described above. However, they do not disclose the specific weight-percent of the chitosan in the polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the weight-percent of the chitosan in the polysaccharide layer to best promote adhesion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

24. Applicant's arguments with respect to Claims 1-22 have been considered but are moot in view of the new ground(s) of rejection necessitated by the Applicant's amendment.

25. In response to applicant's argument that the devices disclosed by Pastorello and Collombel are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Pastorello and Collombel disclose medical implants with coatings for increased tissue compatibility. Although they do not disclose that the coatings can be used specifically on a stimulation electrode, it would have been obvious to one having ordinary skill in the art at the time of the invention to use teachings from these disclosures to solve the problem of adhesion, infection, and biocompatibility of any medical device that is intended for implantation.

26. In response to applicant's argument that Lahtinen does not disclose a stimulation electrode, applicant is directed to Paragraphs 0035 ("pacemaker lead"), 0038 ("stimulation"), and 0141 (metallic pacemaker wires).

27. In response to applicant's argument that there is no suggestion to combine the references due to the fact they are nonanalogous art, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the present case, each reference teaches a feature to increase tissue

compatibility and reduce inflammation of the surrounding tissue. If a specific feature, such as adhesion-promoting chitosan, DMNP, or the use of multiple layers with different properties, is known to provide a function for the greater success of an implantable medical device, there would be motivation for a person having ordinary skill in the art at the time of the invention to add that feature to another implantable medical device coating for greater success of that device.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela M. Bays whose telephone number is (571) 270-7852. The examiner can normally be reached on Monday-Friday, 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Supervisory Patent Examiner, Art Unit 3766

/P. B./
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